## REPORT TITLE

The 60-Day Response by the Endosulfan Task Force to the Environmental Fate and Ecological Effects (EFED) Drafted Risk Assessment for the Reregistration Eligibility Decision On Endosulfan (EFED Memorandum Dated April 13, 2001)

## DATA REQUIREMENT

Not Applicable

## AUTHORS

Richard Allen, Ph.D.
Reinhard Fischer, Ph.D.
Tharacad Ramanarayanan Ph.D.

## PREPARED BY

Aventis CropScience USA LP
P. O. Box 12014
2. T.W. Alexander Drive
Research Triangle Park
North Carolina, 27709

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Endosulfan Task Force
c/o Dr. Bert Volger
Ceres International LLC
1087 Heartsease Drive, West Chester, PA 19382

**Volume 1 of 2**

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No claim of confidentiality is made for any information contained in this study on the basis of its falling within the scope of FIFRA §10(d)(1)(A), (B), or (C).

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Company: Endosulfan Task Force (ETF)

ETF Representative: Bert Volger, Ph.D.

Chair, Endosulfan Task Force

Signature:

Date: November 13, 2001

## STATEMENT OF GOOD LABORATORY PRACTICE

No Good Laboratory Practice Statement is required for the information presented in this volume according to 40CFR Part 160.

Sponsor and Submitter: ________________________
Bert Volger, Ph. D.
Chair, Endosulfan Task Force

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# I. INTRODUCTION

The Endosulfan Task Force (ETF) companies consisting of Aventis CropScience USA LP, FMC Corporation and Makhteshim-Agan of North America Inc. prepared this 60-day response to EPA's initial 'Environmental Fate and Ecological Effects Risk Assessment for the Reregistration Eligibility Decision (RED) on Endosulfan' (EFED memo dated April 13, 2001; DP Barcodes D238673, D191905, D224730, D198346, D259123, D259983, D260709, D262998).

The ETF appreciates the effort and consideration the Agency and in this case EFED has put into this initial risk assessment for endosulfan. The ETF also welcomes the opportunity to comment on it. The ETF realizes that risk assessments for endosulfan are particularly challenging given the wide range of crops treated and long history of use of the compound resulting in a large database of literature information and incident reporting. The ETF has committed substantial resources over the last two decades (since the Registration Standard of April 1982) to generate a comprehensive database in the areas of ecotoxicology, environmental fate and risk assessments in addition to ongoing stewardship programs in support of the subject registrations.

On December 15, 2000, the ETF had provided detailed comments to the draft RED document during the 30-day response period. Only a small number of the ETF's comments and suggestions for corrections of the EFED section were incorporated in the published initial RED document (09/13/01). Based on careful review, the ETF believes that the current draft EFED Chapter still contains significant errors related to data interpretations and the accuracy of the assessments, which are misleading without further correction and refinement. In this response document, the ETF is only addressing those key issues and areas of concern that are presently supported by the ETF data base, and are documented by the current labels of the ETF products. These issues need further clarification and discussion before the final RED should be released.

The ETF's key comments concerning the EFED Chapter are:

- Although EFED describes the aquatic exposure assessment as "non-conservative" some very significant assumptions are at least conservative and in some cases unrealistic.

- The persistence of endosulfan plus its toxic metabolite endosulfan sulfate in soil, water and sediment is overstated.

- EFED's refined risk assessment is based on the use of unrealistic exposure model input parameters and a poorly derived species sensitivity distribution.

- The current buffer does contribute to reducing run-off loads: specific label language to this effect should further ensure the effectiveness of the buffer.

- Available monitoring data do not confirm a widespread contamination of surface water from current US labeled uses.

- Incident reporting (fish kills) does not confirm EFED's assumption of risk and do reflect the improvements in recent years with revised use directions and improved stewardship.

# II. Endosulfan Task Force Response Regarding EFED's Environmental Fate and Ecological Effects Risk Assessment

## *Product Profile*

Endosulfan as a non-systemic insecticide, plays an important role in the control of beetles, caterpillars, weevils, plant bugs, leaf hoppers and miners, flies, thrips and mites. Based on its selectivity towards non-target predators and beneficial insects, as well as its unique mode of action, endosulfan is considered by many growers as an excellent tool regarding insect resistance and integrated pest management (IPM) programs. Information supporting this has been provided to the Agency during the reregistration process (most recently at the 9/28/98 SMART meeting). During its more than 40 year use history, only a few cases of insect resistance have been reported. Therefore, endosulfan still provides a much-needed solution in situations where resistance to other insecticides has developed and no alternatives are available.

During the reregistration process the ETF has been working with EPA, USDA, and grower communities to alter product use patterns, incorporate mitigation measures and develop stewardship programs, so that growers have access to this critical tool and use it in a safe and effective manner.

In view of these efforts and available information, the ETF is disappointed that some of these facts have not been considered by EFED in its initial assessments. The ETF believes that the EFED's draft risk chapters do not represent current use patterns and are based on conservative, unrealistic assumptions. The ETF is taking the opportunity to comment on these assumptions in this response, and is also looking forward to discuss these issues in more detail with the Agency during the next phase of the RED process.

## *Conservatism of the Assessment*

The ETF appreciates that the statements about the conservatism of the risk assessments have been revised to reflect the difference in the terrestrial assessments as screening level (conservative) and aquatic as more refined assessment using typical use rates, one application per year and not considering endosulfan sulfate.

However, the aquatic assessment must also be still regarded as "conservative", as there are a number of issues that could be handled in a manor reflecting more realistic conditions. These are:

- <u>Selection of PRZM and EXAMS hydrological and physical parameters</u>: It is well established that PRZM/EXAMS aquatic exposure assessment is driven by the appropriate selection of parameters that describe the hydrological balance (i.e. runoff) and erosion potential. This was demonstrated for endosulfan specifically in a sensitivity analysis report submitted by ETF to EFED in October 1999 (MRID# 44953101). The parameters selected by EFED in the simulation model are, in many cases, extreme worst-case. An evaluation of EFED's parameter selection is given in the section "Refined Risk Assessment" below.

- <u>Species selection for the probabilistic risk assessment</u>: From the large number of results available, EFED selected only ten aquatic species from the lower end of the sensitivity distribution to represent the aquatic universe.

- Effectiveness of 300-foot buffer: EFED's exposure assessment assumes that the existing requirement for a 300-foot buffer between treated areas and water bodies has no impact in reducing runoff losses at all. This, coupled with the selection of unrealistic input parameters for runoff curve numbers and erosion parameters, implies almost zero infiltration of water crossing the buffer. It is hard to envisage a real-life example of such a scenario.

- Pesticide Input Parameters: In an aerobic aquatic metabolism study the half-life for the degradation of the total toxic residue (α- plus β-endosulfan plus endosulfan sulfate) was 19 days. This is supported by additional studies in the public literature. However EFED has used a values of 114 days and 416 days for the two isomers of endosulfan, respectively.

  It should be noted in this context that the term "total endosulfan" is used differently by the ETF and EFED. While the ETF uses "total endosulfan" for the sum of the toxic moieties of α-endosulfan, β-endosulfan, and endosulfan sulfate, EFED applies the term only to the sum of α- and β-endosulfan.

- Selection of crop scenarios and application rates: One of the chosen scenarios (lettuce in Tennessee) does not reflect current maximum application rates (EFED used 3x 2lbs ai/A instead of 3 x 1 lb ai/A) and is not representative of the use of endosulfan in this crop. On the other hand one of the major uses of endosulfan (cucurbits) has not been assessed by EFED, but was assessed by the ETF (MRID # 44953103).

The Endosulfan Task Force has already conducted similar refined risk assessments and submitted these to the Agency in October 1999. The risk assessment comprised of three reports:

- selection of model scenarios based on endosulfan use patterns and soil and hydrologic properties in major use areas. (MRID # 44953101)

- a sensitivity analysis for key model input variables (MRID # 44953102)

- a refined risk assessment (MRID # 44953103) including comparison of the distribution of exposures with species sensitivity distribution curves and an attempt to quantify the impact of a 300-foot buffer on runoff losses using a model based on PRZM and developed by Waterborne Environmental Inc. , which was presented at the ACS in March 1999.

The ETF responses draw on the ETF's risk assessment and compare the respective results. The ETF believes that their assessment goes beyond the standard Tier 2 scenarios (and the inherent conservative or unrealistic input parameters used by EFED) and has presented a refined risk assessment based on actual use patterns and areas. The ETF notes that no response to their assessment has been forthcoming from EFED. The ETF believes that this assessment can be used or be developed to refine the aquatic risk assessment for endosulfan in line with EPA's Guidelines on Ecological Risk Assessment and the ECOFRAM guidance document of aquatic risk assessments[1].

[1] USEPA. 1998. Guidelines for Ecological Risk Assessment. EPA/630/R-95/002F, USEPA, ORD, Washington, DC.
USEPA. 1999. Ecological Risk Assessment Framework (ECOFRAM) Aquatic Environment Draft report. U.S. EPA Office of Pesticide Programs.

## *Characterization of the Persistence of Endosulfan and its Toxic Transformation Products*

The ETF does not dispute the rates of degradation and dissipation reported in the chapter but disagrees with some of the conclusions drawn from the data and the subsequent parameterization of model inputs of endosulfan fate. EFED frequently quotes that the half-life for degradation of the total toxic residue (α- plus β-endosulfan plus endosulfan sulfate) is "*in the region of several months to six years*". However, the weight of evidence indicates that the value is always less than 6 months in the field and only in one out of five soils was the half-life for the total toxic residue "in the region of six years". As a consequence, EFED implies that there is potential for accumulation of endosulfan in soil and this increases the risk for runoff. Long-term field accumulation studies in different regions of the world (Tiirmaa & Dorn, 1988; MRID # 45421401) have shown that endosulfan after yearly application of 5.5 to 12.5 kg/ha over a period of 5 to 7 years dissipates within 6 months after the last application to a total residue level of less than 0.1 ppm (soil 0-10 cm). There is no soil accumulation of endosulfan, even after excessively high application rates over many years.

A comparison and consequence of the EFED and ETF approaches to the parameterization of soil and water endosulfan degradation inputs is given in this response under the section **Refined Risk Assessment**.

## *Characterization of the Fate of Endosulfan in Water*

The EFED chapter has concluded that α- and β-endosulfan undergo slow microbial degradation in sediment/water systems, using estimated values that are contrary to experimental findings discussed below. EFED used half-lives of 114 days and 416 days, respectively, as inputs to the EXAMS model. These values were derived by doubling the aerobic soil half-life, according to EFED guidelines (unpublished) if experimental values do not exist. Similarly, anaerobic aquatic half-lives of 286 days and 382 days were used based on a doubling the anaerobic soil half-lives. Although realistic hydrolytic half-lives of 19 days and 10.7 days at pH 7 were used, all these assumptions result in simulations that indicate that endosulfan will persist and accumulate in sediment.

However, the ETF submitted a study to EPA (MRID # 44917801 and # 44917802) demonstrating that in sediment/water systems endosulfan and endosulfan sulfate are readily degraded in both water and sediment phases with half-lives in the total system of 4 to 8 days for endosulfan and 17 to 21 days for the total toxic residue (α- plus β-endosulfan plus endosulfan sulfate). Based on this study the ETF used a lumped degradation half-life for the total toxic residue of 19 days. This is significantly shorter than the value used by EFED and better reflects the fate of endosulfan and endosulfan sulfate in water as observed in experimental studies. As a consequence, the ETF simulations demonstrate no accumulation of residues in water and sediment.

The EFED concluded that the submitted study cannot be used to satisfy the aerobic aquatic metabolism data requirements, but agreed that it does provide some supplemental information about the aerobic aquatic metabolism of the combination of α- and β-endosulfan. EFED did not use the results of the study in selecting the EXAMS parameters. However, there are many other examples in EFED risk assessments where supplemental data have been used to select input parameters.

The ETF accepts some of the limitations of the study conducted in 1985 but strongly believes that the results are indicative of the behavior of endosulfan in water and should be used as "supplemental" information. The reviewer noted four main deficiencies:

1. *The study was conducted with slightly basic to basic sediment and water phases. This may have quickened the hydrolysis process in the system*.

   ETF Response: The Agency notes that the products of hydrolysis were not detected in this study but suggests that the hydrolysis products might have degraded rapidly and so were not observed. The data do not support this hypothesis. In the first 2 to 4 days after application only endosulfan sulfate was detected. The formation of endosulfan sulfate results from microbial degradation. Then, as time progressed the sulfate declined and levels of peak M1 (endosulfan hydroxy acid) increased concomitantly indicating that the major route of degradation was via the sulfate and not the diol. In any case the test system was not unrepresentative of reality. A survey of the NAWQA database has indicated that in areas of endosulfan use, surface water pH is in the region of 7 to 8. Therefore, the combination of hydrolysis to the diol and microbial degradation to the sulfate can coexist.

2. *Extractions did not appear exhaustive*.

   ETF Response: EFED's summary in the RED has concluded that extractions were exhaustive.

3. *The aerobicity of the system was not established at all.*

   ETF Response: Although no measurements of redox potential or oxygen concentration in the water column are reported, the report states that the test systems were constantly agitated using a magnetic stirrer and the enclosed systems flushed with air for 8 hours each day. It is well established over the years by many studies that this incubation system is adequate for maintaining aerobic conditions.

4. *Soil and Waters from Germany were used, and they were not compared to domestic soils and waters*.

   ETF Response: The key parameter of concern is water pH. The ETF has surveyed the NAWQA surface water database for study areas located within the MLRA's considered in the ETF's own risk assessment. A summary of results are presented in the table below and show that the test systems' pH values (7.1 and 7.9) represent over 90% of the water sampled in these five MLRA's:

| **Crop** | **MLRA** | **NAWQA Study Area** | **% of samples with pH** | | |
|---|---|---|---|---|---|
| | | | **< 7** | **7 to 8** | **> 8** |
| **Apples** | 101: Ontario Plains & Finger Lakes | Hudson River Basin | 5 | 68 | 27 |
| **Cotton** | 134: Southern Mississippi Silty Uplands | Mississippi Embayement | 32 | 58 | 9 |
| **Tomatoes** | 155: South Florida Flatwoods | South Florida | 22 | 78 | <1 |
| **Potatoes** | 11A: Central Snake River Plains | Upper Snake River | <1 | 17 | 83 |
| **Cantaloupes** | 11: Sacramento & San Joaquin Valley | Sacramento River Basin | 3 | 80 | 17 |
| | | San Joaquin | 5 | 68 | 28 |
| | | Total (n = 3652) | 6 | 63 | 31 |

In summary, the ETF believes that the above study demonstrates that endosulfan and endosulfan sulfate do not persist in surface water and sediments and that the use of unrealistically long half-life values in the EFED EXAMS simulations significantly over-predicts the persistence and accumulation potential of endosulfan and endosulfan sulfate in water and sediment.

### *Refined Risk Assessment*

The Environmental Fate and Ecological Risk Assessment for the Reregistration Eligibility Decision on Endosulfan concludes in the executive summary that at current use rates *"…endosulfan is likely to result in acute and chronic risk to aquatic species"*.

This conclusion is taken from a comparison of modeled aquatic exposure concentrations using the simulation models PRZM/EXAMS with assessment endpoints (LC50 values) and a review of available water monitoring and incident data. In this segment of the response to the RED, the ETF has compared and contrasted the exposure assessment and evaluation of surface water monitoring data conducted by EFED with that presented by the ETF to EPA in October 1999 and December 2000. As a consequence, the ETF will demonstrate that, with slight modification to the current label language, the risk of endosulfan to aquatic species can continue to be significantly reduced through mitigation measures associated with reductions in spray drift and run-off.

The ETF disputes the results of EFED's Refined Risk Assessment and the conclusions drawn from it as they consider the following have been inadequately or inappropriately addressed:

1. Definition of the total toxic residues.
2. The scenarios selected, which includes location, soils, application regime and other associated information
3. Parameters chosen for aquatic exposure assessment
4. The LC50 distribution used by EFED to define the "aquatic universe"

## Definition of Total Toxic Residue

The approaches taken by EFED and ETF to calculate EECs for endosulfan residues were different. The EFED approach was to determine exposure concentrations for the two isomers of endosulfan ($\alpha$ and $\beta$) and add together to provide an EEC for total endosulfan (i.e. $\alpha$- plus $\beta$-endosulfan) for comparison with ecotoxicology endpoints which are routinely determined on a mixture of the two isomers. Estimates for endosulfan sulfate exposure were based upon comparisons of 82 pairs of STORET monitoring data, which EFED describes as "*… not reliable enough to enable an accurate quantitative assessment of the endosulfan distribution…*". Ratios of endosulfan sulfate to total endosulfan were calculated and the median (0.55) used to estimate endosulfan sulfate concentrations in surface water based on the simulations of parent endosulfan exposure.

The ETF believes this approach to be unnecessarily complicated and potentially misleading within the context of the water resources assessment. The main focus of the risk assessment is on acute exposure i.e. peak or 96 hour average concentrations following runoff or drift to surface water. These events will occur either as a consequence of drift of a mixture of $\alpha$- and $\beta$-endosulfan or via runoff near the time of application when the soil residue will comprise of mainly the two endosulfan isomers and not the degradation product, endosulfan sulfate. Therefore, to assume that the expected level of endosulfan sulfate in surface water will be 55% of these peak endosulfan values is misleading.

## Definition of Use Scenarios for Exposure Assessment

Table 3 of the EFED RED chapter (page 13) lists the label rates for endosulfan uses that were evaluated in the environmental risk assessment. Maximum label use rates and typical rates, supplied by BEAD, were used in the assessment.

The following table compares the use scenarios evaluated by EFED and ETF. The major differences in the two sets of scenarios are the assumptions in the time between applications. No specific timings are listed on the label due to the need to maintain flexibility and to apply when pest pressures demand treatment. However, as the product has been used for many years, it is possible to develop realistic scenarios typical for endosulfan use in rotation with other insecticides to prevent the development of resistance.

Several of EFED's assumptions do not match commercial practice:

- Endosulfan is unlikely to be used at 3-day intervals in cotton, as insecticide applications are made approximately every 10 days and in rotation with other insecticides, and therefore the use of endosulfan will typically cover the whole season with three applications at 30 to 40-day intervals. In fact, EFED used a 30 day to 40 day interval in their estimation of drinking water exposure as shown in Table 6 (page 16) of EFED Chapter. Similarly, for apples, tomatoes and potatoes reapplication of endosulfan within a spray program is unlikely to occur at 7 to 10-day intervals.

- The maximum label rate for lettuce does not reflect current labels. The maximum single application rate allowed is 1 lb. ai/A.

- EFED's 'typical' use rate for cotton (1 x 0.8 lb a.i./A) does not match BEAD's data (1 lb ai/A/season with 0.4 lb ai/A/application). The ETF's scenario is more consistent (3 x 0.4 lb ai/A). The ETF also questions the 'typical' use rate in tomatoes. Data specifically from Florida (Buckley and Associates) indicated that 1 application of 0.75 lb ai/A is most typical.

| Crop | EFED parameters | | | ETF parameters | | | Comments |
|---|---|---|---|---|---|---|---|
| | **Applicat. method** | **Maximum label use rate (lb ai/A)** | **'Typical' use rate (lb ai/A)** | **Applicat. method** | **Maximum label use rate (lb ai/A)** | **'Typical' use rate** | |
| **Cotton** | Aerial | 2 x 1.5 @ 3-d interval | 1 x 0.8 | Aerial | 3 x 1 @ *ca.* 30 to 40-d interval | 3 x 0.4 @ *ca.* 30 to 40-d interval | BEAD use tables supports ETF typical use scenario. |
| **Apples** | Ground blast | 2 x 1.5 @ 10-d interval | 1 x 1.5 | Air blast | 3 x 1 @ *ca*. 30-d to 60-d interval | 1 x 1.5 | Both sets of parameters in general agreement with BEAD data |
| **Tomatoes** | Aerial | 3 x 1 @ 7-d interval | 3 x 0.7 @ 7-d interval | Aerial & Ground | 6 x 0.5 @ 15-d interval | 1 x 0.75 | ETF use data indicate that in Florida (scenario location) 1 application of 0.75 lb/A is typical |
| **Potatoes** | Aerial | 3 x 1 @ 7-d interval | 1 x 0.8 | Aerial | 3 x 1 @ 45-d interval | 1 x 0.8 | Both sets of parameters in general agreement with BEAD data |
| **Lettuce** | Aerial | 2 x 1.5 @ 2-d interval | 2 x 0.7 @ 9-d interval | not performed | | | Current labels only allow a maximum of 1lb ai/A/application |
| **Tobacco** | Aerial | 3 x 1 @ 7-d interval | 1 x 0.9 | not performed | | | |
| **Pecans** | Ground blast | 2 x 1.5 as needed | 2 x 0.9 @ 14-d interval | not performed | | | |
| **Cantaloupe** | Not performed | | | Ground | 3 x 1 lb/A @ 37-d interval | 1 x 1.1 lb/A | |

## Input Parameters Describing the Degradation of Endosulfan

The ETF believes that there is sufficient data available to characterize the exposure of both endosulfan and endosulfan sulfate using the PRZM/EXAMS model. EFED has characterized the absence of an assessment for endosulfan sulfate as further evidence of the conservatism of its approach. However, the ETF believes EFED's decision not to include an assessment of the risk of endosulfan sulfate introduces an unnecessary uncertainty into the assessment process. The ETF incorporated the sulfate into its assessment by considering the exposure to aquatic organisms of the total toxic residue. This is justified because:

- the sorption properties of α-, β-, and endosulfan sulfate are similar
- the toxicity of endosulfan and endosulfan sulfate are similar

The parameter describing the persistence of the total toxic residue (half-life) chosen by the ETF was based on the results of the field dissipation studies (150 days). The ETF understands that EFED prefer to use the aerobic soil metabolism half-life as a PRZM input parameter, mainly because dissipation in the field includes other processes such as runoff, volatilization and leaching. However, in these particular field studies the ETF believes that these processes did not occur because the rate of dissipation of α- and β-endosulfan were equivalent to laboratory degradation half-lives (e.g. if volatilization had occurred, the half-lives of α- and β-endosulfan in the field would have been much shorter). More importantly, the field studies offer a real world environment in which the microbial degradation of endosulfan sulfate can occur. The sulfate only reaches a maximum concentration in laboratory studies after 2 to 4 months. At this point the conditions for microbial degradation of the metabolite within the closed laboratory system are no longer optimal and result in unrealistically long degradation half-lives. Therefore, the use of field dissipation data is justified. The use of a 150-day half-life for the total toxic residue also reflects behavior of α- plus β-endosulfan plus endosulfan sulfate in the field, whilst including the metabolite in the quantitative risk assessment. The following table compares the rates of degradation of α- and β-endosulfan and the total toxic residue in the laboratory and field. It demonstrates that both EFED and ETF model input parameters are both valid. However, the exclusion of endosulfan sulfate by EFED and EFED's comments that by excluding it in the exposure assessment, the risk assessment is conservative, is not correct and misleading.

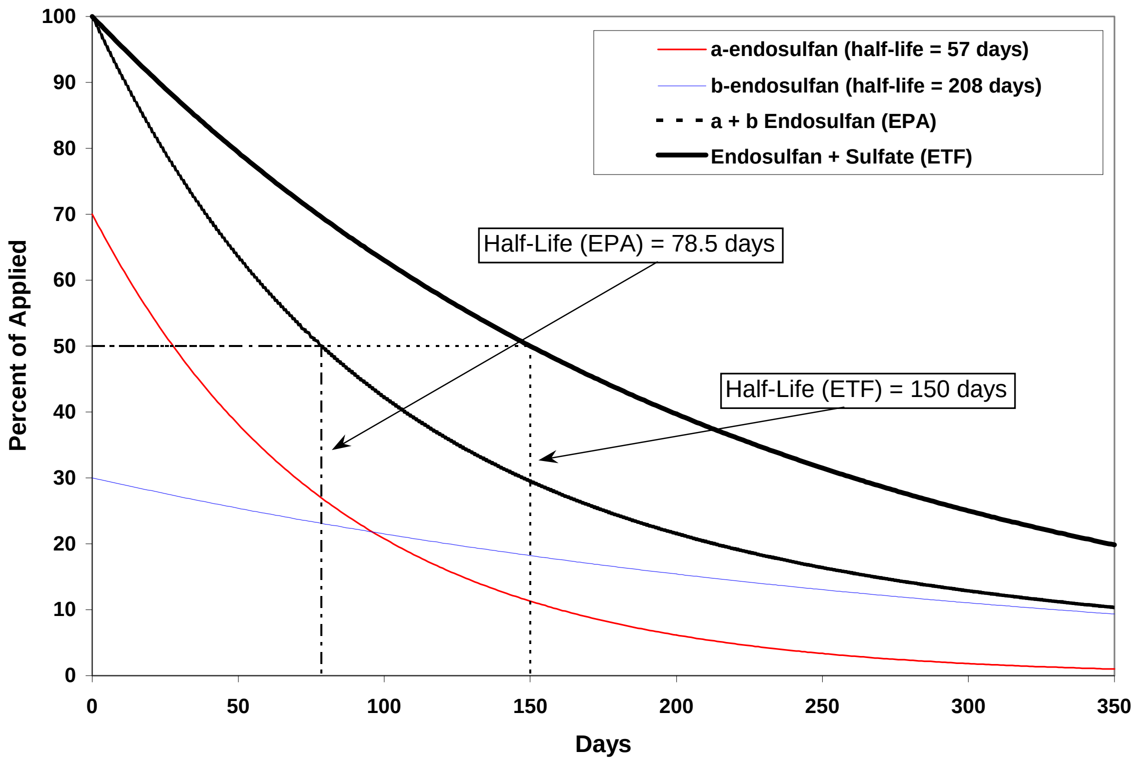
**Comparison of laboratory and field degradation half-lives and input parameter selection**

| | Half-lives (days) | | | |
|---|---|---|---|---|
| | Aerobic laboratory degradation[a] | Field dissipation[a] | EFED Model Input parameters | ETF Model Input Parameter |
| α- endosulfan | 40 (35-67) | 46.5 (6-71) | 57 | NS[b] |
| β- endosulfan | 125 (104-265) | 96 (19-106) | 208 | NS |
| α- + β-endosulfan | 86 (75-125) | 83 (41-93) | NS | NS |
| α- + β-endosulfan + endosulfan sulfate | 392 (288-2148) | 145 (97-172) | NS | 150 |

[a] Values taken from EFED Chapter, not original reports
[b] Not simulated

A comparison of the consequences of the different approaches is shown in the following Figure 1 below and demonstrates that the ETF assumption of a 150-day half-life for the total toxic residue is in fact a more conservative degradation rate than that of EFED (combined half-life of 78.5 days for α- plus β- endosulfan).

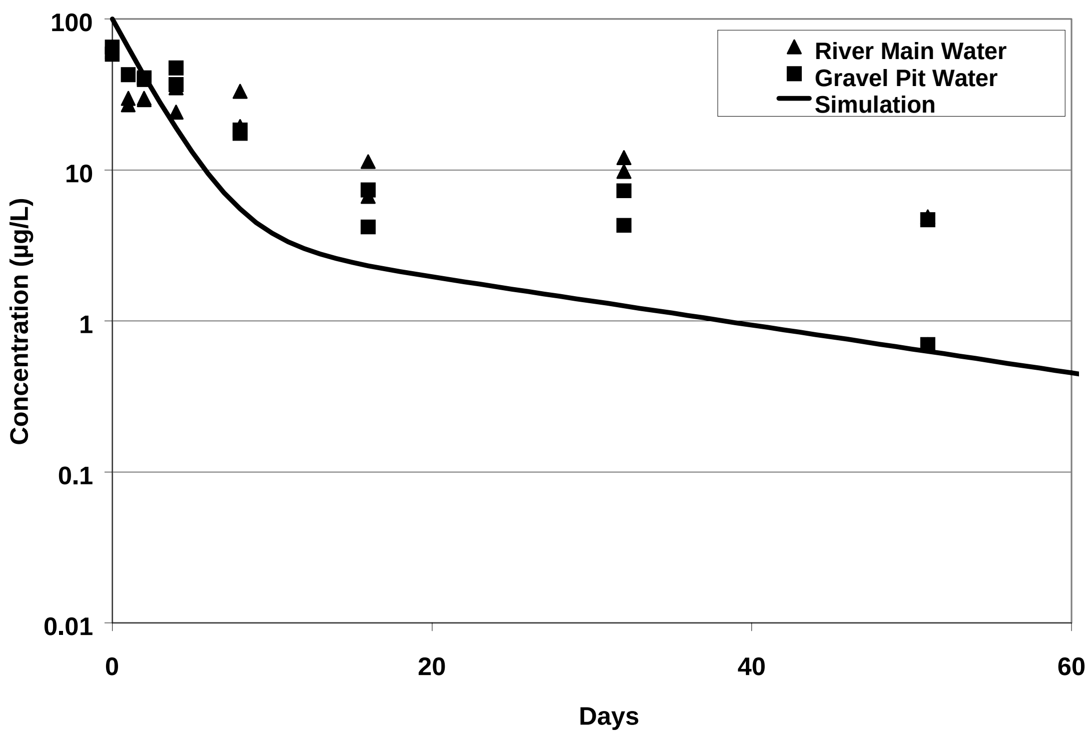
Figure 1. Comparison of Soil Degradation Rates in EFED and ETF Simulations of the Persistence of Endosulfan in Soil




As stated in the Section **Characterization of the Fate of Endosulfan in Water**, the EFED chapter has concluded that α- and β-endosulfan undergo slow microbial degradation in sediment/water systems. Half-lives of 114 days and 416 days respectively were used as inputs to the EXAMS model. However, the ETF used a lumped degradation half-life for the total toxic residue of 19 days based on the results of a sediment/water study. This is significantly shorter than the value used by EFED and better reflects the fate of endosulfan and endosulfan sulfate in water as observed in experimental studies. As a consequence the ETF simulations demonstrate no accumulation of residues in water and sediment.

The impact of these two sets of assumptions is shown in Figure 2. This shows that using the ETF assumptions the total toxic residue (endosulfan plus endosulfan sulfate) in water (and sediment) readily declines over time, whereas in EFED's assumptions endosulfan itself is significantly more persistent.

Figure 2 Comparison of Fate of Endosulfan in Surface Water Based on EPA and ETF Model Input Parameters




## Hydrological and Physical Parameters

The ETF submitted a report in October 1999 of the sensitivity of key model input parameters on outputs such as runoff volume, mass of eroded soil and pesticide fluxes (MRID # 44953102). This report concluded that for PRZM hydrological physical parameters were found to a have a higher significance to transport endosulfan to surface water bodies than the compound-specific parameters. This result justified the rigorous scenario selection procedure used by the ETF for defining the exposure assessment scenarios. EFED have not documented the selection criteria for their exposure assessments.

There is significant discrepancy in the input parameters chosen by ETF and EFED for runoff and erosion parameters. As an example the runoff curve numbers used in comparable scenarios are summarized in the following table.

| Scenario | Runoff Curve Numbers | | | | | | Comments |
|---|---|---|---|---|---|---|---|
| | ETF | | | EFED | | | |
| | F | C | R | F | C | R | |
| Apples – New York | 77 | 73 | 75 | 94 | 84 | 89 | EFED used Cabot silt loam (group D soil), ETF used Collamer silt loam (group C). ETF values taken from PRZM manual for woods in poor conditions during winter and fair condition in summer. No rationale given for EFED values. EFED's Fallow & Residue curve numbers exceed the value recommended by the PRZM manual for a farm track (87). |
| Cotton - Mississippi | 91<br>88<br>88 | 88<br>84<br>84 | 88<br>82<br>83 | 99<br>94<br>99 | 93<br>84<br>83 | 92<br>83<br>83 | Both scenarios used Loring silt loam (Class C). ETF values are consistent with PRZM manual recommendations. EFED values exceed PRZM manual recommendations especially for fallow periods. EFED uses 99 whereas manual recommends 91. A hard surface road is 90! |
| Tomatoes – Florida | 91 | 76 | 84 | 98 | 98 | 98 | EFED uses a Felda sand (class B/D). Curve numbers of 98 for all periods is unrealistic. A hard surface road CN = 84 to 92 for this range of hydrologic class soils! |

F= Fallow, C = Cropped, R = Residue. The three sets of values for cotton reflect conservation tillage practices in 2$^{nd}$ and 3$^{rd}$ year.

The Runoff curve numbers selected by EFED in these scenarios are, in many cases, unrealistic. Therefore, any attempt to use more 'conservative" input parameters (e.g. with respect to typical application rates vs. maximum application rates) is overshadowed by the use of these sets of input parameters. According to the sensitivity analysis conducted by ETF (MRID# 44953102) on PRZM input parameters, the relative sensitivity of runoff curve number is 6.5, meaning that every unit increase in curve number will yield approximately 6.5 times more runoff. For example in the tomato scenario, EFED used a curve number of 98 instead of 76 as recommended by the PRZM manual. This could potentially translate in significantly more runoff volume than the realistic value. This is probably the most significant reason why EFED's risk assessment resulted in highly unrealistic risk estimates.

In conclusion, the ETF believes that the parameters selected by EFED in their scenarios are extreme worst-case and, in some cases, totally unrealistic. These parameters overshadow any attempts to introduce more 'conservative' assumptions with respect to application rates or degradation parameters. As a consequence the simulated losses of endosulfan to surface water are significantly overestimated by EFED. Also, the Agency has not accounted for the mitigation offered by a 300-foot buffer on runoff losses. Therefore, the ETF concludes that the simulations presented in the EFED chapter do not represent the expected distribution of endosulfan residues in aquatic environments in the real world.

The ETF has quantified the impact of a 300-foot buffer on runoff and erosion losses through the use of a model based on PRZM and developed by Waterborne Environmental Inc and presented at the American Chemical Society Symposium in March 1999. The model considers infiltration of runoff water into the buffer and retardation of eroded particles as a consequence of surface roughness. The model was calibrated using the South Carolina runoff study (MRID # 41309701). Using the calibrated model, the effect of the 300-ft buffer on runoff was examined for cotton and tomato scenarios and concluded that the buffer would result in 60 % to 90 % reduction in losses from the edge of the treated area.

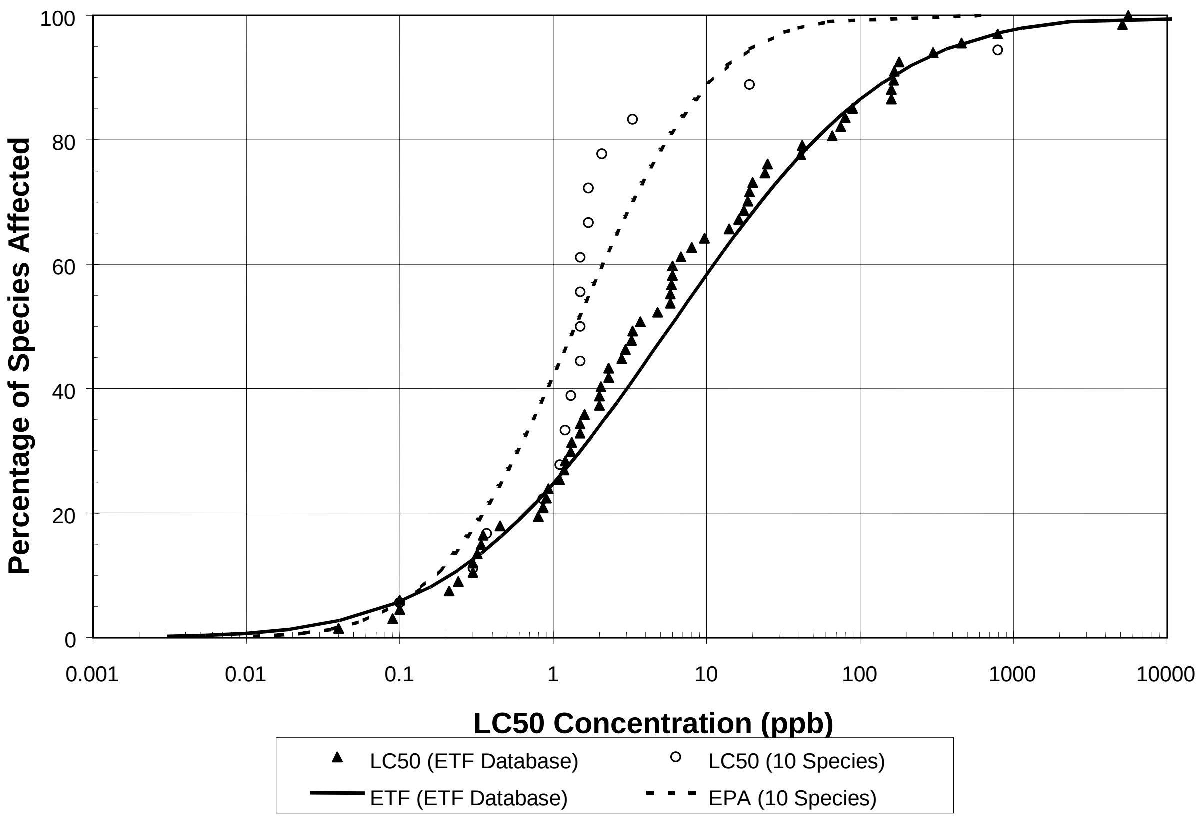
## Representativeness of “Aquatic Universe” Chosen

The conservative approach to the risk assessment is also evident from the organism selection EFED has chosen to represent the “aquatic universe”. Of the ten species selected, five are freshwater organisms (all fish), and five are marine/estuarine representatives (two fish, three invertebrates). While on one hand EFED complains (page 17) that only a few surrogate species are tested to represent all freshwater and estuarine/marine animals, on the other hand EFED selects only a small sub-portion of the endosulfan test results available, which are from the “more sensitive” organisms. For instance, no freshwater invertebrates, such as the standard test organism *Daphnia magna*, are part of the “aquatic universe”. On page 19, EFED states that “*estuarine/marine organisms generally were more sensitive to the effects of endosulfan than their freshwater counterparts*”, but half of the organism in the list to represent the “aquatic universe” are from the “more sensitive” group. The proportion of fresh water and marine/estuarine species chosen by EFED does not reflect the proportion of endosulfan usage in these respective areas. Therefore, EFED’s selection is biased and does not reflect the real world picture of endosulfan aquatic toxicity in view of its geographic use pattern. It undermines the accuracy of the assessment and represents (another) conservatism in the risk assessment.

In addition, parameters that define the log-normal distribution used to describe the LC50 distribution seem to be erroneous according to the information provided in the RED (Appendix I; Tables I-1 and I-2). The mean and standard deviation (SD) of natural-logarithmic (LN) transformed data should be 0.59 and 1.91, respectively instead of 0.326 and 1.64. If geometric mean for *Oncorhynchus mykiss, Pylodictus olivarius* and *Lepomis macrochirus* were used instead of the individual data points, the mean and SD of the LN-transformed data would be 0.8 and 2.46, respectively.

On the other hand, ETF used a broader range of the available LC50 data, which included the marine/estuarine fish species that are more sensitive. The following figure illustrates the difference between the cumulative distribution plots of LC50 used by EFED and ETF. The plot not only shows the biased nature of the distribution used by EFED, but also shows that the log-normal distribution defined by the EFED, does not fit the data (for 10 species) very well.

Figure 3: Comparison of Species Sensitivity Distributions used by EFED and ETF




## Joint Probability Curves used to Define Risk

As a result of
(a) the selection of overly conservative parameters for exposure assessment simulation,
(b) the non-consideration of the effect of 300-ft buffer on runoff loading, and
(c) the use of effects distribution derived from a small subset of the available data,
the Joint Probability Curves (JPC – also known as risk curves) generated by EFED showed unrealistic risk.

The following figures compare the risk curves resulted from ETF's risk assessment (MRID # 44953103) with those generated by EFED. These comparisons were conducted only for apples, potatoes, cotton and tomatoes, as they were the only common scenarios chosen by both ETF and EFED. The plots also show the effect of the buffer concerning runoff loading, resulting in reduced risk to aquatic organisms. Contrary to EFED's unrealistic risk estimates – "*more than 90% of the time roughly 60% of the aquatic species will express a 50% mortality rate*" for tomatoes, ETF's risk curves show that less than 10 % of the time the total endosulfan concentrations will be greater than the LC50 values for less than 8 % of the species. In the case of cotton, the risk estimates are similar to tomato scenario.

Figure 4: Comparison of risk curves for Apple scenario

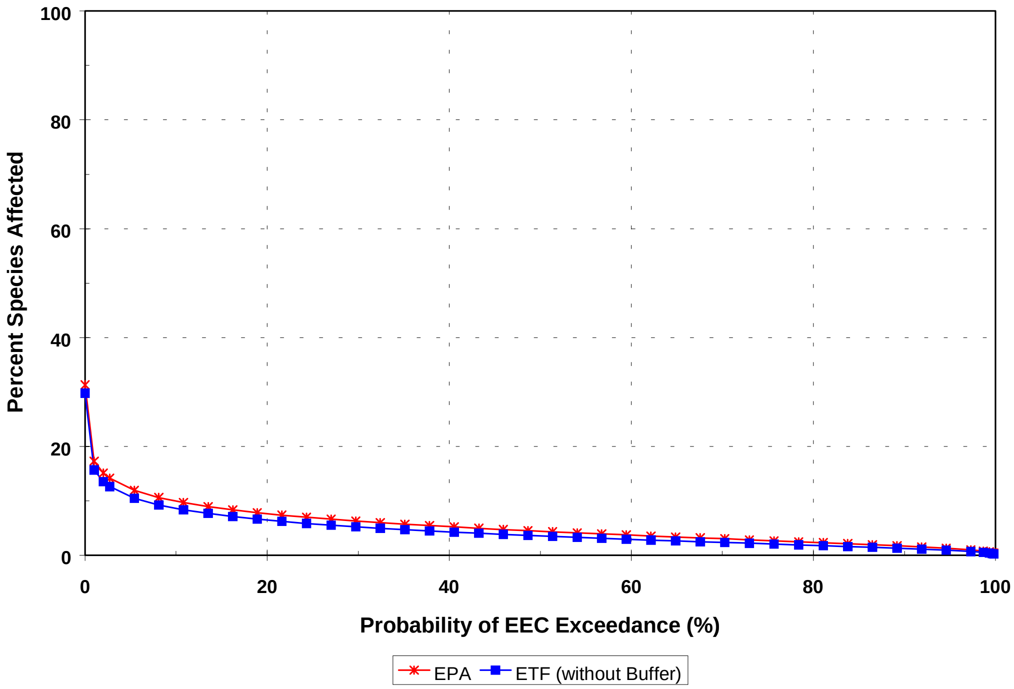



Figure 5: Comparison of risk curves for Potato Scenario

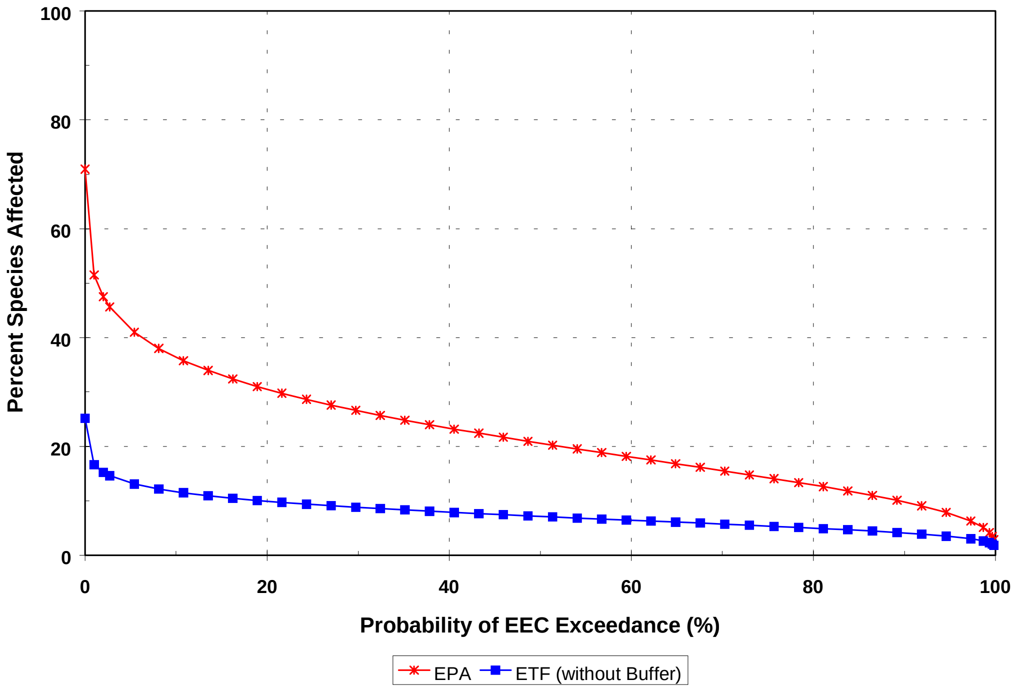


Figure 6: Comparison of risk curves for Cotton Scenario

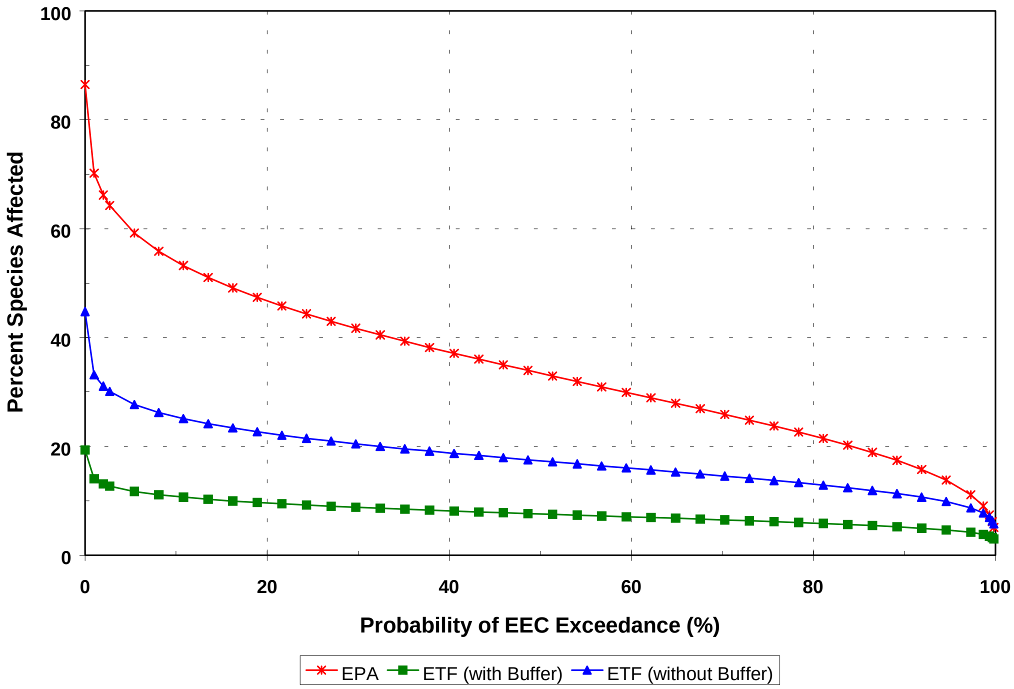
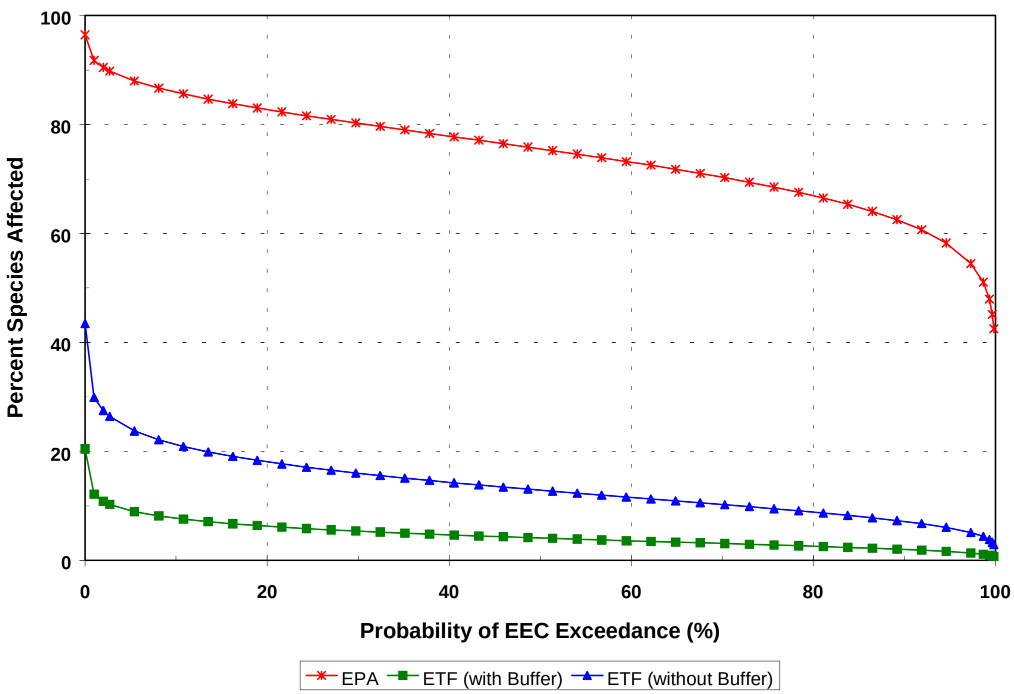



Figure 7: Comparison of risk curves for Tomato Scenarios



## *Terrestrial Exposure Values*

The Agency in their response to ETF's 30-day comments has acknowledged that only a screening level risk assessment was performed. As the risk assessment resulted in a concern for terrestrial organisms, a more refined assessment should be conducted. Instead of theoretical calculations based on Hoerger & Kenaga modified by Fletcher, actual plant residue values should be used. The ETF submitted in 1987 (MRID# 40261301) a risk evaluation of endosulfan to avian species including product specific plant residue data and its crop specific half-lives (123 trials from 18 different crops). This response was submitted in support of the revised maximum label rate (3 lbs./A/year). Assuming a NOEL of 30 ppm (Mallard Duck Reproduction) and given the crop specific residue half-lives (2.2 to 4.5 days) for total endosulfan measured at day of application (93 ppm) and two weeks thereafter (0.5 ppm), the risk to terrestrial organisms is acceptable. The ETF would like to emphasize that "total endosulfan" in this context is the sum of α-endosulfan plus β-endosulfan plus endosulfan sulfate.

## *Data Gaps*

The acute aquatic toxicity data for endosulfan sulfate (see recent submissions: MRID # 45421402, # 45421403) confirm the same toxicity level of endosulfan sulfate and its parent. Since the sulfate is not more toxic than the parent compound, the requirement of additional studies with this metabolite would not result in different results.

## *Consideration of Current Mitigation / Stewardship Efforts and the Runoff Buffer*

EFED states in various places in the document that fish kill incidents continued basically unchanged after the introduction of the 300-ft buffer as a mitigation measure. In its 30-day response the ETF demonstrated that especially for California, where this and other mitigation measures were introduced, the rate of fish kills did indeed decline. Out of the 29 reported cases in California, 20 were recorded in the '70s, 5 in the '80s, and 4 in 1996. Only ONE case in 1996 was observed after a "registered" use (8 cases in the '70s, one in the '80s).

EFED supports their conclusion that the current label-language with respect to the buffer is ineffective in mitigating runoff losses with comments from the USDA NRCS publication "Conservation Buffers To Reduce Pesticide Loss". In particular they state that a runoff buffer must be specifically designed to reduce runoff. The ETF agree that current label language needs further improvement and is awaiting the final Spray Drift Label Directions as recently proposed in order to implement it; but ETF does not understand EFED's position that a 300-foot buffer will not reduce losses. In reality an area of land 300-foot wide that separates the treated field and a water body will possess characteristics that will reduce runoff losses. For example uncultivated land will tend to have hydraulic properties that result in greater infiltration rates than the cropped field. It is unrealistic to assume that these buffer areas will have runoff and erosion properties like those selected by EFED in their PRZM simulations.

## *Use and Interpretation of Surface Water Monitoring Data*

### EPA-STORET

EFED had analyzed all the available monitoring data in STORET in a lumped manner rather than a chronological manner. A chronological analysis of the data will highlight the effect of the introduction of the label restrictions on the levels of endosulfan detected in the surface waters. The ETF submitted a detailed analysis of STORET data along with other sources of monitoring data such as USGS-NAWQA and California DPR Surface Water Database. The analysis showed that the introduction of use restrictions resulted in significantly lower concentrations and in most cases no endosulfan residues were detected in surface waters.

## USGS-NAWQA

The ETF had pointed out in its 30-day response to the draft RED the existence of endosulfan monitoring data in the USGS-NAWQA database. However, EFED noted that "*The dissolved concentrations the ETF refers to in their response are from analyses of sediment. These concentrations are not relevant to concentrations in the water body* . . ." (page 25 EFED Response to Registrant 30-day comments). ETF wishes direct EFED again to the web-link already provided in the 30-day response (http://infotrek.er.usgs.gov/wdbctx/nawqa/nawqa.home). This address links to the interactive search tool in the NAWQA database. The ETF found dissolved total endosulfan (Parameter number 39388) monitoring data. There are 130 data points taken from Florida, Nebraska, New Mexico, Oregon, and Washington from 1991 to 98. The ETF downloaded the parameter description file from the same location (under Glossary section) and checked the description for Parameter Number 39388, which is "Endosulfan I, Total (µg/L); Medium: Water". EFED in its response perhaps was referring to Parameter 49332, described in NAWQA parameter description as "Endosulfan I BM < 2µ; Medium: Sediment", which is the sampling of Bed Sediments. The ETF requests the EFED to download the NAWQA parameter description file (http://infotrek.er.usgs.gov/pls/nawqa/docs/HELP/PARAMETERS.ZIP) in order to clarify its position.

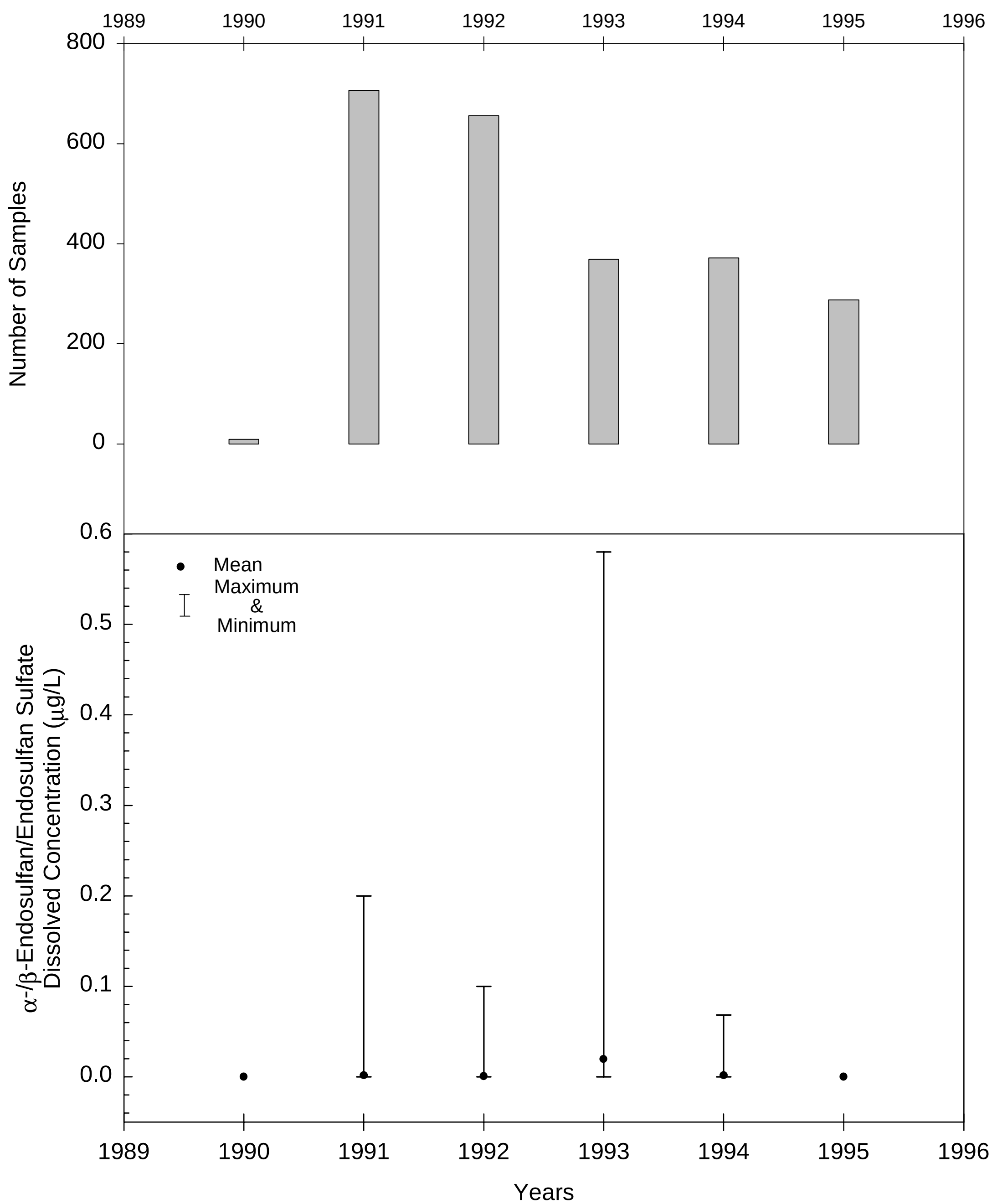
## CA-DPR

The California Department of Pesticide Regulations published its surface water database and is now available at http://www.cdpr.ca.gov/docs/surfwatr/surfdata.htm and also in CD-ROM. This database contains water quality data from 16 counties in California sampled from January 1991 through March 2000. Endosulfan and endosulfan sulfate data was derived from this database and analyzed. Figure 8 shows that, as with STORET data, the California surface water database also shows significantly reduced detection after 1993 (< 0.1 µg/L).

EFED in its Response to ETF 30-day comments notes that "… *given endosulfan's expected behavior in water, monitoring data with infrequent sampling intervals is unlikely to detect the peak concentrations of endosulfan in water and that it is these concentrations that are most likely to cause the fish kills*" (Page 25). In 1993 a detailed study[2] was initiated with a joint effort from California DPR and California Department of Fish and Game (CDFG) monitoring the Sacramento (Nov. 1993 to 1994), Merced (June 1994 to 1995), Salinas (July 1994 to 1995) and the Russian (August 1994 to 1995) Rivers. Water samples were collected from these rivers every week (for one year) and analyzed for insecticide residues, including endosulfan. It should be noted that endosulfan was not detected in any of the samples collected.

[2] Ganapathy, C., Nordmark, C., Bennet, K. and Bradley, A. 1998. Temporal Distribution of Insecticide residues in Four California Rivers. Report # EH97-06, California Department of Pesticide Regulation, Sacramento, CA.

Figure 8 Maximum, Minimum and Mean Endosulfan and Endosulfan Sulfate Concentration Quantification Reported in California Surface Water Database



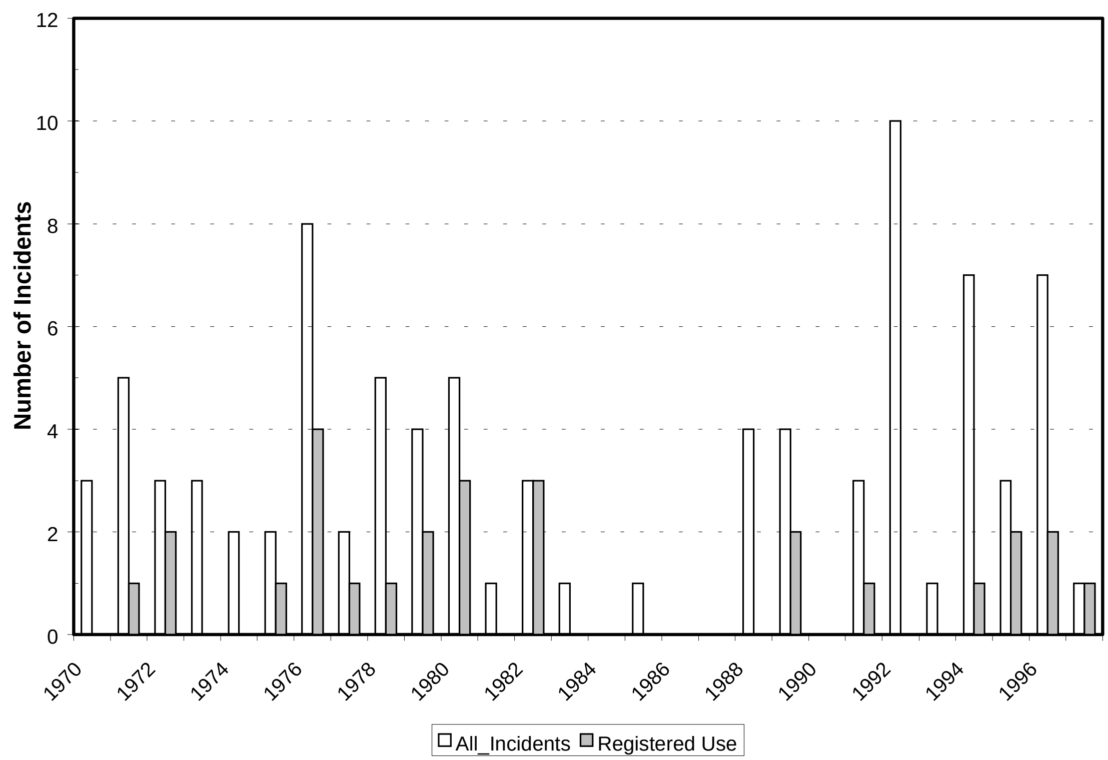
### *Interpretation of Incident Data*

In a number of different places (e.g. pages ii, 24, 25, 28, 31, 33, 38) of EFED's Risk Assessment document, references are made to the incident database (Ecological Incident Information System) reporting of endosulfan effects to various organisms. EFED uses the reported incidents to verify the correctness of their risk assessment and associated Risk Factors. The ETF strongly disagrees with this interpretation for a number of reasons. For instance, EFED conducted the analysis on all incidents data, which includes "accidental" and "intentional misuse" and concluded *"... that current use patterns of endosulfan represent a threat"* (page 28).

EFED's statistical analysis (Appendix G) and their conclusions were based on 91 (of 95 total) reported incidents (86 aquatic + 9 terrestrial). Out of the 91 incidents reported over the last 30 years of endosulfan use, only 26 are attributed to "registered use" and 32 are attributed to either "accidental" or "intentional misuse". Incidents related to misuse do not prove the Agencies' assumptions. Similarly, the incidents where the actual use is "not reported" (18 cases) or "undetermined" (15 cases) cannot be attributed to endosulfan as there is at least a 50% chance (based on the proportion of "registered use" to "misuse") that it might as well have been from "misuse". Just <u>assuming</u> that endosulfan was the cause of these incidents because of its high fish toxicity is neither scientific nor justifiable.

Again, EFED's statement "*multiple fish kill incidents attributable to endosulfan use are reported each year*"(pages ii and 25) is simply not true. During nearly 50 % of the years (13 out of 28) there were no incidents that were attributed to registered use of endosulfan (Figure 9). Indeed, this confirms that EFED's risk assessment, which concluded "*a 90% probability that roughly 60% of all the aquatic species will suffer 50% mortality for the most vulnerable uses*", is unrealistic and over-conservative. Taking this prediction and the fact into consideration that there are at least several thousand endosulfan applications each year, a similar high number of reported fish kills would be reported; but instead EIIS records indicate that one sees about one fish kill every other year. This reality contradicts EFED's risk assessment (as stated by EFED: "*in any given year, we would expect a high likelihood that nontarget fish mortality would result from endosulfan use. Indeed, this is confirmed by incidents reported in the EIIS, which show multiple incidents per year, even in the years since the buffer language was added to the label.*" – page 25).

Figure 9: Summary of incidents data




It must be concluded that contrary to EFED's repeated assertions, when viewed unbiased, the incident data do not confirm EFED's assumptions, but are indicative of the conservative and unrealistic nature of the assumptions.

### Analytical issues

The analytical confirmation of fish kills is an important part of the incidents reported. This is especially true because of the high fish toxicity of endosulfan, which makes it an easy explanation for any fish kill. Analytical methodology problems are reported by at least some authors, e.g. when it is stated that the analytical quantification is difficult or that endosulfan could not to be or could not always be chromatographically resolved from other analytes. This is not a question of resolving the isomer identity (as EFED states in its reply to the ETF's 30-day response), but the fact that it is often difficult to confirm endosulfan peaks in the presence of some naturally occurring substances. For that reason confirmation of endosulfan residues with a second method become important, if an unequivocal identification of the residues is desired. As a result of these admitted shortcomings the ETF believes that the incident database over-reports and misrepresents the actual cases/fish kills caused by endosulfan.

## ***Toxicity to Plants***

The incident reports on plants are sketchy at best. When examining the 5 non-target plant claims in the incidents database, four are listed as "**aquatic**" under the column "TYPEINCID". One study is listed as "TERRES/AQUAT/TPLANT". Three of the incidents present neither a number of affected organisms, nor a type of a response (UNKNOWN/UNDETERMINED) leaving doubts if "incidents" or indeed plant effects were reported here. Two of the alleged plant incidents have numbers of affected organisms associated, incident B0000-218-16 lists “500” and incident B0000-231-01 “2000”. While B0000-218-16 lists “lettuce” as affected species, B0000-231-01 gives “safflower”. For both incidents the “TYPEINCID” is given with “**aquatic**”, in both cases the response is “UNKNOWN”. At least in the database available to the ETF there is no indication that the plants were “killed”, as alleged by EFED. The incidents occurred in 1975 and 1971, respectively, and were entered in the database 1997. At least in the database there is no information on likely other causes of plant effects (if these were indeed plant effects and not aquatic effects in the vicinity of the fields) such as residues of herbicides that may have remained in the tank. Over 30 years of endosulfan years in many countries has not resulted in complaints about phytotoxicity. Even the incidents in the database (if true) were only reported in the seventies, only from California, and never again. The absence of such data from all other states and times makes the early entries highly suspect. Such poor data should not be used as proof for “phytotoxicity” or in any assessment.

## *Miscellaneous Issues and Error Corrections*

### Maximum single application rate for lettuce and potatoes

After reexamination of the labels cited by the Agency in their review of ETF’s 30-day response, which include the labels of Phaser 50WSB (EPA Reg. No. 45639-194, 45639-198, dated 3/8/2000), Thionex 50WP (66222-02, 4/8/95), and Thiodan 50WP (279-1380, 9/3/98), the ETF confirms that the highest single application label rate for lettuce and potatoes is indeed 1.0 lb a.i./A. The WSB/WP labels supported by the ETF state the application rate as “1.5 to 2 lbs. per acre”, but not as “1.5 to 2 lbs. a.i. per acre”, which is cited by the Agency. The Thiodan/Phaser WSB and WP labels refer to amount of product (containing 50% of endosulfan active ingredient) per acre. Thus a rate of 1.5 to 2 lbs (product) per acre is equivalent to a rate of 0.75 to 1.0 lb a.i./Acre per application (3 applications and 3 lb a.i./A/season).

### Additional studies

The ETF requests that the additional important publications listed in its 30-day response to be considered for the chapter addressing the long-range transport of endosulfan: (Bidleman et al.,1990, Organic Contaminants in the Northwest Atlantic Atmosphere at Sable Island,1988-1989, Chemosphere; 1992, p.1389-1412; Hoff et al., 1992; Annual Cycle of Polychlorinated Biphenyls and Organohalogen Pesticides in Air in S. Ontario; Environm.Sci.Technology; 1992, 26,2; 166-175; Simonich & Hites, 1995; Global Distribution of Persistent Organochlorine Compounds; Science; 1995; 269; 1851- 1854). Based on these publications endosulfan is detectable only in very low concentrations in the air during the time of application and decreases to extremely low levels during off-season. The extremely low traces occasionally found in remote areas were not confirmed in each case.

### Bird toxicity values

The ETF is asking EPA again for the following changes:
The $LD_{50}$ for bobwhite was reported in MRID# 137189 as 42 mg/kg (as stated on page 86). For ducks, the range of $LD_{50}$ values (28 to 33 mg/kg) for the different studies (see p.86) should be reported [in summary Table 9] instead of just the lowest value. In summary table [10] either means, medians, or ranges should be reported instead of the lowest value; e.g. the available results for the 96-hr LC50 Trout using endosulfan technical, range from 0.8 to 1.5 ppb; reported was the lowest value (0.8 ppb).

While EFED rejected the initial request by stating that the most sensitive endpoints are used in the initial deterministic risk assessment, the presentation of ONLY the lowest values in a table of results, independent from the further use in one or another type of a risk assessment, presents a bias in the documentation of results for the public. This is especially indicated as EFED is performing also a refined risk assessment using a range of data.

### Actual Use Characterizations for CA

Some of the values [reported in Table 17, page 34 for typical and seasonal application rates in CA] reported by EFED are incorrect. The highest seasonal application rates e.g. for tomatoes are up to 4 times (12.7 lb a.i./A) of the maximum allowable seasonal label rate. Also the lowest reported rates (lettuce 0.03 lb a.i./A) are below any effective (and recommended label) application rate.

## III. CONCLUSIONS

The inherent toxicity of endosulfan to aquatic species is effectively managed through the use of label restrictions, which have been developed by the member companies of the Endosulfan Task Force.

The ETF believes that restrictions on maximum and seasonal applications and the requirement for a 300-foot buffer between treated areas and water bodies mitigates the risk to aquatic organisms. The ETF has demonstrated in this response that the EFED chapter of the RED significantly over-estimates risk as a consequence of parameter selection, especially for runoff and the assumption that the current 300-foot buffer has no impact on runoff losses. Also, EFED has mischaracterized the distribution of the sensitivity of aquatic organisms to endosulfan.

On the other hand, ETF's assessment conducted prior to the publication of the RED and submitted to EPA in October 1999 has demonstrated that a truly refined risk assessment will result in acceptable risk, if it is assumed that the buffer will reduce runoff losses by 60% to 90%. This is supported by the infrequent number of incidents from registered uses of endosulfan.

EFED's statements that for some scenarios or crops, there is a 90% probability that 60% of the organisms will be exposed to concentrations that exceed the LC50, is extremely misleading and unrealistic when compared to the number of incidents as a result of "registered use" of the product. The ETF requests that its comments are taken into account by EPA during the upcoming phases of the RED process and is prepared to work with EPA to further refine the risk assessment supporting further amendments to the label language in order to achieve the necessary mitigation required by risk managers